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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,761	02/07/2005	Bernard Charles Sherman	PT-2099001	1380

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EXAMINER

PALENIK, JEFFREY T

ART UNIT	PAPER NUMBER
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4133

MAIL DATE	DELIVERY MODE
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11/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,761

Applicant(s)

SHERMAN, BERNARD CHARLES

Examiner

Jeffrey T. Palenik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7 Feb 2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-6 are presented and represent all of the claims under consideration.

Priority

This application is the National Stage filing of International Patent Application No. PCT/CA03/01175, filed 6 August 2003 and claims the benefit of prior-filed Canadian Application No. 2,395,819, filed 13 August 2002. Examiner finds that Applicant's filing meets the priority requirements and determines the earliest effective foreign filing date to be 13 August 2002.

Information Disclosure Statement

An Information Disclosure Statement filed 7 February 2005 is acknowledged and has been reviewed.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

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Claim Objections

Claims 5 and 6 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative and/or cannot depend from any other multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 5 and 6 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Krishnamurthy et al. (U.S. Patent 6,419,960).

Krishnamurthy et al. teaches an oral modified/controlled release drug formulation that provides rapid initial onset effect and a prolonged duration of effect (claim 1). Drug release in “two spikes” (i.e. bimodal release) is taught (column 4, lines 44-51). Methylphenidate (“MPH”) formulations are taught (column 3, lines 29-31; Example 6) as the object of the invention. Polyvinyl acetate phthalate (“PVAP”) is taught as an enteric coating for the drug formulation (column 9, lines 41-49). Example 6 demonstrates a formulation whereby the enteric polymer is incorporated in the form of beads at 91.4% whereas the drug (e.g. methylphenidate hydrochloride) is present at 6.5%. Thus, the ratio of the drug to the enteric polymer used in the formulation is 1:14.1. Clearly the MPH is taught as being the main component and the PVAP is

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a coating clearly contemplated for the MPH. Therefore, each and every element of the claims is met by the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devane et al. (U.S. Patent 6,228,398).

Devane et al. teaches a multiparticulate modified release composition that delivers an active ingredient in a bimodal manner (Abstract). Methylphenidate HCl is clearly the main active agent that is taught (claim 13) and clearly contemplated as the only agent taught (see Examples). Example 1 teaches formulations of methylphenidate hydrochloride mixed with different functionally equivalent release coatings such as polyvinyl pyrrolidone and Eudragit®.

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Polyvinyl acetate phthalate is clearly taught as a coating to be used with the active agent methylphenidate HCl. However, Devane does not teach the specific ratios claimed.

In the very least, polyvinyl acetate phthalate is taught as another coating material that is a functional equivalent to the aforementioned coating materials in that it also modifies the release of the active ingredient (column 8, line 62 to column 9, line 1). One of ordinary skill in the art at the time of the invention would therefore, have been motivated to substitute polyvinyl acetate phthalate as a functionally equivalent coating material in the composition with a reasonable expectation that bimodal release of the active agent (e.g. methylphenidate) would be retained and since its use is clearly conceived of as a coating on the only active agent contemplated in the invention, namely Methylphenidate HCl. Furthermore, the adjustment of particular conventional working conditions (e.g., determining result effective amounts of the ingredients beneficially taught by the cited references, especially within the broad ratios instantly claimed), as well as using a functionally equivalent coating material, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

No claims allowed.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-270-2966.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey T. Palenik
Patent Examiner


JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER